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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/521,109 | 01/11/2005 | Francesco Tedesco | 50294/016001 | 5428 |

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| EXAMINER | |
|---|---|
| VANDERVEGT, FRANCOIS P | |
| ART UNIT | PAPER NUMBER |
| 1644 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 11/14/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/521,109 | TEDESCO ET AL. | |
| | Examiner | Art Unit | |
| | F. Pierre VanderVegt | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *37 and 39-79* is/are pending in the application.

4a) Of the above claim(s) *50-55,57 and 59-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,39-41,47,49,56,58 and 77-79* is/are rejected.

7)☒ Claim(s) *42-46 48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This application is a Rule 371 continuation of PCT Serial Number PCT/EP03/078487.

Claims 1-36 and 38 have been canceled.

New claims 77-79 have been added.

Claims 37 and 39-79 are currently pending.

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, claims 37, 39-49, 56, and 58, in the reply filed on September 5, 2007 is again acknowledged. New claims 77-79 read upon the elected invention and are included in the subject matter of this Office Action.

2. **Claims 50-55, 57, and 59-76 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 5, 2007.

Accordingly, **claims 37, 39-49, 56, 58 and 77-79 are the subject of examination** in the present Office Action.

**In view of Applicant's amendment filed March 21, 2008 no outstanding grounds of rejection are maintained.**

The following represent NEW GROUNDS of rejection and this Office Action is made NON-FINAL.

Applicant's arguments with respect to claims 37, 39-49, 56, 58 and 77-79 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 recites the limitation "The chimeric protein" in line 1. There is no antecedent basis for this limitation in the claim. Claim 49 is an independent claim and therefore there is no earlier recited "chimeric protein" for the claim to refer to. Applicant should amend the claim by changing the article from "The" to --A--.

Claim 47 recites the limitation "murine heavy gamma chain, and rattus norvegicus heavy chain" in lines 3-4. There is no antecedent basis for this limitation in the claim. Base claim 37 recites that the antibody is a "human antibody." Accordingly, there is no basis for reciting the heavy chain from a different species in a dependent claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 49 is rejected under 35 U.S.C. 102(a,e) as being anticipated by US 2003/0039649 A1 to Foote (B on form PTO-892).

The '649 publication teaches a polypeptide sequence that comprises instantly claimed SEQ ID NO: 10 as SEQ ID NO: 28. Merely reciting that the claimed protein is "chimeric" in the instant claim does not distinguish the claimed polypeptide from the prior art. The prior art teaching anticipates the claimed invention.

5. Claim 49 is rejected under 35 U.S.C. 102(a,e) as being anticipated by US 2004/0001822 A1 to Levanon et al (C on form PTO-892).

The '822 publication teaches a polypeptide sequence that comprises instantly claimed SEQ ID NO: 10 as SEQ ID NO: 82. Merely reciting that the claimed protein is "chimeric" in the instant claim does not distinguish the claimed polypeptide from the prior art. The prior art teaching anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 37, 39-41, 56, 58, and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitch (Circulation [1999] 100:2499-2506; cited on form PTO-1449, of record) in view of U.S. Patent No. 5,770,429 to Lonberg et al (A on form PTO-892, newly cited).

Fitch teaches a pharmaceutical composition comprising the humanized scFv form of the antibody 5G1.1, which blocks the conversion of activated human C5 to C5a and C5b (see entire reference, Abstract in particular). The claim is drafted in an open format, in that the target C5 polypeptide "comprises" the KDMQLGRLHMKTLLPVSK sequence of human C5. The claim does not require that the antibody binds to the recited sequence, only that the antibody binds to a polypeptide comprising the sequence. Accordingly, any antibody that binds to human C5 and inhibits C5 conversion to C5a and C5b satisfies the metes and bounds of the claim. The prior art teaching anticipates the claimed invention.

Fitch does not teach fully human antibodies.

The '429 patent teaches:

> "One of the major impediments facing the development of in vivo therapeutic and diagnostic applications for monoclonal antibodies in humans is the intrinsic immunogenicity of non-human immunoglobulins. For example, when immunocompetent human patients are administered therapeutic doses of rodent monoclonal antibodies, the patients produce antibodies against the rodent immunoglobulin sequences; these human anti-mouse antibodies (HAMA) neutralize the therapeutic antibodies and can cause acute toxicity. Hence, it is desirable to produce human immunoglobulins that are reactive with specific human antigens that are promising therapeutic and/or diagnostic targets. However, producing human immunoglobulins that bind specifically with human antigens is problematic" (Column 1, lines 54-67 in particular)

The '429 patent teaches transgenic mice that, when immunized with an antigen, produce fully human [claims 3, 4] antibodies to that antigen (see entire patent).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to make a fully human antibody to human C5. One would have been motivated, with a reasonable expectation of success, to make an anti-C5 antibody for therapeutic application as taught by Fitch, but make it fully human according to the method of the '429 patent. One would have been motivated to make fully human anti-C5 antibodies for therapeutic applications because a fully human antibody would be even less likely to stimulate an anti-antibody response in a human subject than even a humanized antibody, which still comprises a nominal amount of murine sequence.

Claims 51 and 77-79 are included because Fitch does not disclose the particular sequences present in the anti-C5 antibody, but silence about a particular property does not necessarily constitute its absence. Applicant's identification thereof may only amount to further characterization of an otherwise old product. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

***Conclusion***

7. Claims 42-46 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/
Patent Examiner
October 20, 2008

/Eileen B. O'Hara/
Supervisory Patent Examiner
Art Unit 1644